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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,336	06/28/2005	Sergio Fantini	10851-008US1	2806
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EXAMINER ABRAHAM, SALEU M				
ART UNIT 3768		PAPER NUMBER		
NOTIFICATION DATE 12/11/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/507,336

Applicant(s)

FANTINI, SERGIO

Examiner

SALIEU M. ABRAHAM

Art Unit

3768

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
Paper No(s)/Mail Date 12/22/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1- 11 and 14 - 24, drawn to a system for detecting a region of a tissue sample having an absorption level different from a background optical absorption level, classified in class 600, subclass 473.
 - II. Claims 12-13 and 25-33, drawn to a method of calculating an absolute oxygenation level of a region of a tissue sample, classified in class 600, subclass 323.
 - III. Claims 34-48 drawn to a method of determining whether a tumor in a tissue sample is malignant or benign, classified in class 600, subclass 425.

The inventions are independent or distinct, each from the other because:

2. Inventions II and I are related as are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another materially different process. (MPEP § 806.05(e). In this case the apparatus as claimed can be used to practice another materially different process such as to quantify disease risk resulting from the application of spectroscopic tissue analysis methods using non-ionizing radiation to

detect pre-disease transformations in the tissue, which increase the risk for this disease in mammals.

3. Inventions III and I are related as are related as are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another materially different process such as to quantify disease risk resulting from the application of spectroscopic tissue analysis methods using non-ionizing radiation to detect pre-disease transformations in the tissue, which increase the risk for this disease in mammals.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Inventions III and II are related as combination and subcombination respectively. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed

does not require the particulars of the subcombination as claimed because the method of determining whether a tumor in a tissue sample is malignant or benign can be achieved by using/measuring a different hemodynamic parameter such as blood flow rate. The subcombination has separate utility such as in optical spectroscopy-based measurement and assessment of skin burn degree or wound healing.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Peter Fasse (Reg. No. 32,983) on 11/21/08 to

request an oral election to the above restriction requirement and this resulted in applicant's election without traverse of Group III, directed to claims 34-48.

7. Claims 1- 33 are withdrawn from further consideration pursuant to 37 CFR 1.42(b) as being drawn to a nonelected Group, and, therefore, Examiner will examine claims 34-48.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
9. Claims 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fantini, S. et al., "Assessment of the Size, Position, and Optical Properties of Breast Tumors in Vivo by Non-Invasive Optical Methods", Applied Optics 37, 1982-1989, 1998; hereinafter **Fantini** in view of US Patent No. 7,006,676 to Zeylikovich (**Zeylikovich**).

In Reference to Claims 34 and 42

Fantini teaches a method of determining whether a tumor in a tissue sample is malignant or benign, comprising:

Re claim 34 -- (a) selecting two wavelengths of light to minimize a difference between relative changes in intensity of light transmitted through the tumor for the two wavelengths, wherein the relative changes in intensity of the light for each wavelength are measured relative to a background intensity of light transmitted through the sample **(see page 1983, para. 1-3 and figure 1);**

(b) obtaining measures of background reduced scattering coefficients of the sample at the two wavelengths **(see page 1983, para. 1-3);**

(c) calculating an absolute oxygenation level of the tumor in the sample by using the relative changes in intensity of the light for the two wavelengths and the measures of the background reduced scattering coefficients of the sample for the two wavelengths **(see page 1987, para. 1);**

Re claim 42 -- a) obtaining thicknesses of the sample and intensities of light transmitted through the sample at a plurality of locations for two wavelengths of light **(see table 2);**

(b) calculating spatial second derivatives of products of the sample thicknesses and the intensities of the transmitted light at the locations for the two wavelengths of light **(see figures 2 and 3 and page 1984);**

(c) calculating an oxygenation level of the tumor based on the spatial second derivatives for the two wavelengths of light, the molar extinction coefficients of oxy-hemoglobin for the two the wavelengths of light, the molar extinction coefficients of hemoglobin for the two wavelengths of light, relative changes in intensity of the light for the two wavelengths of light and the measures of the background reduced scattering

coefficients of the sample for the two wavelengths of light (**see table 3 and discussion section, pp. 1987-1988**); and

(d) calculating an oxygenation level of non-tumor regions of the tissue sample based on the spatial second derivatives for the two wavelengths of light, the molar extinction coefficients of oxy-hemoglobin for the two wavelengths of light, the molar extinction coefficients of hemoglobin for the two wavelengths of light, relative changes in intensity of the light for the two wavelengths of light, and the measures of the background reduced scattering coefficients of the sample for the two wavelengths of light (**discussion section, page 1987**).

However, Fantini is silent with respect to classifying a tumor as malignant or benign. Zeylikovich, in the same field of endeavor, discloses methods and apparatus for detecting abnormalities in host media such as a patient's breast (**see abstract and column 2, lines 21-30**). He further cites the invention's benefit in utilizing "optical imaging techniques" for detecting "suspicious masses" within a patient's breast and differentiating the detected tumor as benign or malignant by totally non-invasive means (**see column 2, lines 35-44**) in addition to providing improved image contrast and resolution over the state of the art (**see column 3, lines 14-19**). Lastly, he discloses abnormality characterization metrics substantially equivalent to applicant's whereby various oxygenation levels and other physiological parameters that improve the reliability of detection are determined and used "to accurately characterize the nature of an abnormality" (**see column 3, lines 19-21 and columns 15, lines 47-67 and 16,**

lines 1-66).

Therefore, it would have been obvious to one of ordinary skill at the time of the invention to have incorporated the tumor differentiation protocol of Zeylikovich in the invention of Fantini in order to provide an improved and more accurate means for obtaining higher contrast and resolution images of breast tumors and determining whether they are malignant or benign as taught by Zeylikovich.

In Reference to Claims 35 – 41

Fantini in view of Zeylikovich has been shown to teach all limitations for claim 34.

Fantini in view of Zeylikovich further teaches a method of determining whether a tumor in a tissue sample is malignant or benign:

Re claims 35-37 – wherein the tissue sample is selected from the group consisting of breast tissue, brain tissue, and muscle tissue (**see Fantini abstract**), the two wavelengths of light are in the near infrared spectrum (**see Fantini abstract**), and the difference between the relative changes in intensity is zero (**see Zeylikovich figures 3a – 3c and column 12, lines 18-52**),

Re claim 38 – wherein the absolute oxygenation level of the tumor is calculated using a formula SO 2 (**see Zeylikovich column 16, lines 46-66**),

Re claims 39-41 – further comprising: illuminating the sample with a plurality of wavelengths of light; and detecting light transmitted through the sample at a plurality of locations (**see Zeylikovich column12, lines 18-52 and claims 16 and 17**), displaying an image of the absolute oxygenation level at the plurality of locations within the tissue sample (**see Zeylikovich figures 3a – 3c, column 12, lines 17-21 and claim 16**), and storing values of the absolute oxygenation level of the tumor in a computer-readable medium (**see Zeylikovich column7, lines 4-19 and 47-52**).

In Reference to Claims 43 – 48

Fantini in view of Zeylikovich has been shown to teach all limitations for claim 42.

Fantini in view of Zeylikovich further teaches a method of determining whether a tumor in a tissue sample is malignant or benign:

Re claims 43-44 – wherein the tissue sample is selected from the group consisting of breast tissue, brain tissue, and muscle tissue, and the two wavelengths of light are in the near infrared spectrum (**see Fantini abstract**),

Re claim 45 – wherein the oxygenation level of a region of the sample is calculated using a formula OL (**see Zeylikovich column 18, lines 8-25**),

Re claims 46-48 – (see rejection for claims 39-41).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alfano et al., Azar et al., Barbour et al., Bernreuter, Franceschini et al., Godik, Grenier et al., Hoogenraad et al., Lilge et al., Nelson et al., and Scharf et al. have been included because they all teach the use of optical transillumination imaging systems and methods for identifying or detecting abnormal anatomical regions or function in vivo similar in scope to applicant's proposed invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 8:30 am - 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/2/08 SA

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768